National Marrow Donor Program®

Entrusted to operate the
C.W. Bill Young
Cell Transplantation Program

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April 30, 2008

Commander Russell Shilling, USN
Program Officer, Medical Services Corps
Office of Naval Research (ONR 341)
875 N. Randolph St.
Arlington, VA 22203

Subject: **Quarterly Performance/Technical Report of the National Marrow Donor Program®**

Reference: Grant Award #N00014-06-1-0704 between the Office of Naval Research and the National Marrow Donor Program

Dear Commander Shilling:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of January 1, 2008 to March 31, 2008.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at cabler@nmdp.org).

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

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Dennis Confer, MD, Chief Medical Officer, NMDP, letter only
Michelle Setterholm, NMDP letter only

NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Grant Award N00014-06-1-0704

QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
JANUARY 01, 2008 to MARCH 31, 2008

Office of Naval Research

And

The National Marrow Donor Program
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14. ABSTRACT

1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation**:** Create a platform that facilitates multicenter collaboration and data management.

15. SUBJECT TERMS
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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QUARTER PROGRESS REPORT

Development of Medical Technology for Contingency Response to Marrow Toxic Agents

January 01, 2007 through March 31, 2007

TABLE OF CONTENTS

IIA. Contingency Preparedness – Hypothesis 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians	
IIA.1.1 Aim 1: Secure Interest of Transplant Physicians	**The NMDP works to educate physicians and their medical staff as well as to disseminate information about its contingency planning through this AIM.** **Period 6 Activity:** • Graded 34 BRT exams submitted by RITN centers; total submitted BRT exams is now 828 • Initiated coordination of Advanced Radiation Medical Emergency training course through the Radiation Emergency Assistance Center/Training Site (REAC/TS) o There will be at least two classes each two days in length with room for 35 attendees in each class, course schedule includes: ▪ Basic Health Physics & Radiation Protection: Part I ▪ A History of Serious Radiological Incidents: The Real Risk ▪ Health Physics & Contamination Control: Part II ▪ Radiation Detection, Monitoring & Protection Laboratory Exercise & Quiz ▪ Diagnosis & Management of the Acute Radiation Syndrome (ARS) ▪ Diagnosis & Management of Internal Contamination ▪ Diagnosis & Management of Acute Local Radiation Injury & Case Review: Yanango Peru Incident ▪ Radiation Sources & Radiological Terrorism ▪ Radiation Emergency Area Protocol Demonstration ▪ Radiation Emergency Medical Management Drill ▪ Radiation Dose Estimations – Problem Solving Session

IIA.1.2 Aim 2: GCSF in Radiation Exposure	**This AIM focuses on non-transplant treatment guidelines and patient assessment related to the use of GCSF for patient treatment as a result of radiation exposure.** **Period 6 Activity:** • No Activity this period
IIA.1 3 Aim 3: Patient Assessment Guidelines	**This AIM focuses on transplant treatment guidelines; including the refinement of guidelines for patient assessment, product selection and transplant in radiation exposure situations.** **Period 6 Activity:** • No activity this period
IIA 1.4 Aim 4: National Data Collection Model	**The focus of this AIM is to define and develop a national data collection and management model to collect data from a mass radiological exposure event.** **Period 6 Activity:** • No activity this period
IIA. Contingency Preparedness – Hypothesis 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.	
IIA.2.1 Aim 1: Contingency Response Network	**Efforts related to this AIM are focused on the develop the Radiation Injury Treatment Network (RITN), a permanent organization of transplant centers, donor centers and cord blood banks to maintain a contingency response network.** **Period 6 Activity:** • Hired an Emergency Preparedness Specialist to assist in the management of RITN. **Exercises:** • Began planning for functional exercises of the NMDP Emergency Operations Response plan in July. **Meetings:** • Formalized the relationship between RITN and ASBMT and between RITN and AABB through a Memorandum of Understanding.

	• Held three (3) conference calls with RITN centers to assist in completion of required tasks and to improve integration into the network. **Communications:** • Developed a modification of the NMDP contact database (POLITE) to specify RITN medical directors, and two coordinators. It was identified during the TOPOFF4 exercise that a centralized calling list of RITN contacts was not accessible by participants. • Conducted a Network communication test with the NMDP Network in January. **RITN development:** • Expelled a RITN center for failure to complete all FY07 tasks in a timely manner; bringing the total number of RITN centers to 52 (36 transplant centers, 9 donor centers, and 7 cord blood banks). • Presented RITN overview to International attendees of the CIBMTR/ASBMT Tandem meeting. Dr. Confer presented a RITN overview to the EBMT Nuclear Accident Committee, this resulted in discussions about further collaboration between RITN and EBMT for crisis response planning.
IIA.2.2 Aim 2: Sibling Typing Standard Operating Procedures	**This goal of this AIM is to develop and test standard operating procedures, in conjunction with core transplant centers, to manage the activities required to HLA type siblings of casualties to evaluate their potential as HSC donors for their affected family member.** **Period 6 Activity:** • No activity this period
IIA. Contingency Preparedness – Hypothesis 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
IIA.3.1 Aim 1: I.S. Disaster Recovery	**The focus of this AIM is to ensure NMDP's ability to access and utilize its information management and communication infrastructure in a contingency situation in which its Minneapolis Coordinating Center is damaged or destroyed.** **Period 6 Activity:** • **Business Continuity Planning:** o Emergency communications:

- Implemented the protection of 82 voice and data circuits connected to the NMDP Coordinating Center with the National Communications System Telephone Service Priority (TSP) program. TSP identifies communications lines that require priority repair in the event of a service disruption.
- Successfully tested the Coordinating Center's public announcement system; verifying its functionality and the training of staff on its operation.
- Initiated the expansion of contacts in the bulk telephonic notification system to include all NMDP Network centers. This will allow for rapid notification of the Network in the event the Coordinating Center is not operational.

- Continued to develop the Business Impact Analysis (BIA) by working with key NMDP departments to identify critical areas that would have high impact to operations if left inoperable.
- Completed development of continuity books for distribution to NMDP operated centers during center site visits this spring and summer. Books are a template of simple preparedness information to assist in the event of a crisis.
- Continued to develop a business continuity plan incorporating a Critical Staff Recovery Site (CSRS) with no initial cost to the organization
- Coordinated fire extinguisher training for Repository staff as part of the HRSA required mitigation plan in preparation for the training to be held early next quarter. Procured and installed weather radios at Coordinating Center Reception and the Sample Repository, this will allow for advanced warning for a variety of hazards ranging from severe weather to chemical spills.

IIB. Rapid Identification of Matched Donors – Hypothesis 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.	
IIB.1.1 Aim 1: Increase Registry Diversity	**Period 6 Activity:** Six contracted HLA testing laboratories performed HLA-A, B, DRB1 typing on all newly recruited donors. • Completed testing of 43,709 newly recruited volunteer donors • Blind quality control testing error rate average was 0.02%, satisfying the project requirement of ≤ 1.5% • On-time testing completion rate was 97%, meeting the project requirement of 85% of typing results reported within 14 days from shipment of samples Contracts for the six laboratories were extended for 3 months. Extension period is March 31, 2008 to June 29, 2008. A Request for Quotation (RFQ) is being prepared and will be released in May, 2008.
IIB.1.2 Aim 2: Evaluate HLA-DRB1 High Res typing	**Period 6 Activity:** This task is closed.
IIB.1.3 Aim 3: Evaluate HLA-C Typing of Donors	**Period 6 Activity:** This task is closed.
IIB.1.4 Aim 4: Evaluate Buccal Swabs	**Period 6 Activity:** In September, 2007, a Sample Storage Research Study (SSRS) was initiated to determine the usefulness of donor buccal swab samples, stored over time, for HLA testing. During this quarter: · Results were received for the First Time Point of the Quality Control (QC) sample portion of the study. HLA results were 100% accurate for Intermediate and High Resolution typing. DNA Evaluation was completed and all sample results were reported. · The next time point for the QC sample portion is June, 2008.

IIB 1.5 Aim 5: Enhancing HLA Data for Selected Donors	**Period 6 Activity:** This aim consists of two prospective, registry-based typing projects, which have the potential to strategically identify and improve the HLA typing and availability of donors most likely to match searching patients from domestic TCs. The primary goal of the Replacement Donor Pilot Study was to identify an HLA-A, B, DRB1 identical replacement donor for every donor selected for workup by a TC. • NMDP staff continued to monitor the patient-directed utilization of donors typed through the project. Donor utilization will be analyzed and reported at regular intervals. The primary objective of the Optimum Donor Pilot Study was to develop a systematic strategy to classify adult donors into phenotype categories based upon the likelihood to appear on a patient's search. Adult donors with high potential to match searching patients were selected and proactively contacted to verify availability, upgrade HLA, and/or secure additional stored samples in an effort to increase the utilization of NMDP donors and to help reduce the search times for patients. • NMDP staff continued to monitor the patient-directed utilization of donors typed through the project. Donor utilization will be analyzed and reported at regular intervals.
IIB. Rapid Identification of Matched Donors – Hypothesis 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.	
IIB 2.1 Aim 1: Collection of Primary Data	**Period 6 Activity:** No activity this period.
IIB 2.2 Aim 2: Validation of Logic of Primary Data	**Period 6 Activity:** This task is closed.
IIB 2.3 Aim 3: Reinterpretation of Primary Data	**Period 6 Activity:** This task is closed.

IIB 2.4 Aim 4: Genotype Lists & Matching Algorithm	**Period 6 Activity:** No activity this period.
IIB. Rapid Identification of Matched Donors – Hypothesis 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.	
IIB.3.1 Aim 1: Phase I of EM Haplotype Logic	**Period 6 Activity:** No activity this period.
IIB 3.2 Aim 2: Enhancement of EM Algorithm	**Period 6 Activity:** No activity this period.
IIB 3.3 Aim 3: Optimal Registry Size Analysis	**Period 6 Activity:** No activity this period.
IIB 3.4 Aim 4: Target Under-represented Phenotypes	**Period 6 Activity:** No activity this period.
IIB 3.5 Aim 5: Bioinformatics Web Site	**Period 6 Activity:** No activity this period.
IIB 3.6 Aim 6: Consultants to Improve Algorithm	**Period 6 Activity:** The funding on this Aim supports the Search Strategy Advice (SSA) program provided to TCs to support their need for expert HLA expertise. The program includes external and internal HLA experts who review each patient search and write a report summarizing a search strategy; both internal and external experts participate in a rigorous QC program. This report assists the TC in rapidly identifying the best potential stem cell source for their patient. The experts also guided development and performed technical validation of enhancements for the HapLogic II algorithm, which was launched in January 2008. The SSA program completed 343 patient reports for 81 TCs during this quarter (January 2008 – March 2008).

	The average turnaround time for all reviews was 3.9 business days which exceeded our program requirement of 5 business days.
IIB. Rapid Identification of Matched Donors – Hypothesis 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.	
IIB.4.1 Aim 1: Expand Network Communications	**Period 6 Activity:** Not activity this period.
IIB.4.2 Aim 2: Central Contingency Management	**Period 6 Activity:** Central Contingency Management uses trained NMDP coordinating center staff to provide comprehensive donor/cord selection recommendations and patient search monitoring for TC staff. Navy funds support the expansion of the Central Search Support (CSS) service for contingency management. During the quarter the NMDP conducted a physician advisory meeting at the 2008 BMT Tandem meetings. Four NMDP network transplant center medical directors participated in the meeting. NMDP staff provided an overview of CSS and a medical director currently utilizing the service provided a summary of their experience. NMDP staff then mediated a discussion to gather feedback on how CSS could potentially benefit the transplant centers and whether the service could be further tailored to meet their needs. Based on post-meeting questionnaires, all attendees felt this service could be beneficial to their centers. Two transplant centers that participated in the advisory meeting requested a trial run with CSS to further evaluate the service. During this quarter one additional member transplant center adopted this service for all new patients and CSS became a requirement for all Affiliate member transplant centers. 185 reviews were completed representing a 38% increase over last quarter. The continued expansion of CSS increases the NMDP's capabilities to provide centralized rapid turnaround search support in the event of a contingency event.

IIC. Immunogenetic Studies – Hypothesis 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.	
IIC.1.1 Aim 1: Donor Recipient Pair Project	**Period 6 Activity:** In 1994 a retrospective Donor/Recipient Pair HLA typing project to characterize class I and class II alleles of donor/recipient paired samples from NMDP's Repository was initiated. The goals of this ongoing research project are to assay the impact of DNA-based HLA matching on unrelated donor transplant outcome, develop strategies for optimal HLA matching, evaluate the impact of matching at alternative HLA loci on transplant outcome and finally to promote the development of DNA-based high resolution HLA typing methodologies. • The data audit process of SG18, which consisted of 425 donor/recipient and 75 cord/recipient paired samples, was initiated with completion expected early next quarter. • The period of performance for SG19 began on January 2, 2008 and ends April 30, 2008. SG19 consists of 489 donor/recipient pairs and 11 cord/recipient pairs. • Preparation of SG20 was started by selection of 409 new donor/recipient pairs and 91 cord/recipient pairs. Ongoing IT support and maintenance of project tasks continued in this period.
IIC. Immunogenetic Studies – Hypothesis 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.	
IIC 2.1 Aim 1: Analysis of non-HLA loci	**Period 6 Activity:** In 2005 a pilot study to perform high resolution KIR gene typing was launched. The primary objectives of the study were to move technology forward from the current practice of locus level typing to high resolution typing, disseminate information and protocols in an open source mechanism and develop reference lines for use in individual laboratories. The IPR database application will allow for storage and analysis of all immunogenetic data collected on NMDP research samples. • The Scientific Services and Bioinformatics departments continued to collaborate on the design and development of the IPR database application and tools to support immunogenetic testing projects

	• A software programmer was contracted to support the development of IPR based on the program specifications prepared by the IPR development team • Development began on the IPR components to facilitate data loading, comparison and processing into the IPR database. • Discrepancy, ambiguity and no-make analysis and resolution of Phase 1, 2 and 3 KIR Typing Pilot project data continued. • A collaboration was initiated with the IHWG KIR project to investigate the role of inhibitory KIR polymorphisms in transplant outcome. An abstract entitled, "Rethinking KIR Haplotype Analysis", was presented at the KIR Polymorphism Workshop at Trinity College, Dublin, Ireland on 13th March, 2008.
IIC 2.2 Aim 2: Related Pairs Research Repository	**Period 6 Activity:** Sample collection began with the release of FormsNet 2.0 on December 3. Sixty seven samples were received, processed and accessioned into inventory during the past quarter bringing the total to 69 samples (32 complete pairs). During the past quarter the Research Repository team completed the specifications for tools to facilitate the receipt, processing, storage and retrieval of the related samples. Tool programming was interrupted due to loss of the project programmer. A new programmer was identified and tool development will resume next quarter.
IID. Clinical Research in Transplantation – Hypothesis 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.	
IID.1.1 Aim 1: Observational Research, Clinical Trials and NIH Transplant Center	**Period 6 Activity:** • The Cord Blood Research sub-Committee submitted and presented a study proposal designed to evaluate the NMDP cord blood transplant experience to date to the CIBMTR Graft Sources Working Committee. The proposal was accepted as a study and protocol development will proceed in July 2008. • Data collection was completed on a pilot study to evaluate the impact of transient warming events on cord blood units. The data analysis is in process and will be summarized next quarter.

IID.1.2 Aim 2: Research with NMDP Donors

Period 6 Activity:

The Role of Culture in Unrelated Stem Cell Donation Galen Switzer, University of Pittsburgh; NMDP IRB-2006-0180

Study Summary

This study aims to examine the role of ethnic group membership and factors associated with ethnic group membership (eg: culturally-based traditions/beliefs) in predicting (a) potential donors' decisions of whether or not to donate hematopoietic stem cells (HSCs), and (b) the health experiences of unrelated donors who actually donate HSCs.

Study Progress

- NMDP completed first full year of consent-to-contact calls on April 18, 2008.
- Status to-date:

	Study Group 1a (CT Continue)	Study Group 1b (CT Opt Out)	Study Group 2a (Donors at WU)
Total Randomized *(April 07-Present)*	281	461	138
Total Decline at Consent to Contact *(April 07-Present)*	8	34	2
Total Currently Active Post Consent to Contact	71	86	100
Total Interviews (T1)Completed by University of Pitt	143	52	81
Total Interviews (T2)Completed by University of Pitt			72
Total Interviews (T3)Completed by University of Pitt			0

	KIR Donor-Recipient Incompatibility in Children with High Risk AML COG Study AAML05P1 NMDP IRB-2007-0212 **Study Summary** This is a prospective Phase II clinical trial of unrelated donor HCT in patients with high risk AML in which KIR typing of the patients and up to 5 potential donors will be available to the treating transplant physician at the time of donor selection. Accrual to this study will continue until 160 patients have received HCT from an adult unrelated donor. It is anticipated this will take 4 years and a total accrual of 400 patients total to achieve this goal. **Study Progress** • IRB approval in place for six COG Transplant Centers • Two patients enrolled to date o Patient 1 ▪ KIR typing completed on three donors ▪ One donor at WU; May 2008 collection date scheduled o Patient 2 ▪ Donor selection for KIR typing completed 4/28/08
IID.1.3 Aim 3: Expand Immuno-biology Research	**Period 6 Activity:** The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies and held an annual committee meeting during the BMT Tandem meetings • One oral abstract was presented at the BMT Tandem annual meetings • Several draft manuscripts are in process • Eight new proposals were reviewed at the IBWC meeting and 6 accepted as studies for initiation in July 2008 • The IBWC annual activity summary was distributed during the BMT Tandem meetings and noted the publication of 11 peer-reviewed manuscripts during CY2007 • The IBWC leadership continued collaboration with the IHWG Hematopoietic Cell Transplant

	Component to provide data and sample support to the upcoming 15th International Histocompatibility Workshop. Funding for CIBMTR IBWC studies: • Funding provided support for DNA extraction of 3400 samples from the NMDP Research Sample Repository to facilitate rapid SNP genotyping for several IHWG/CIBMTR projects • A call for grant requests was distributed to the full IBWC to solicit applications for funding. The application period closes early next quarter

ACRONYM LIST

AABB	American Association of Blood Banks	IND	Investigational New Drug
AML	Acute Myelogenous Leukemia	ICRHER	International Consortium for Research on Health Effects of Radiation
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IS	Information Services
ASBMT	American Society for Blood and Marrow Transplantation	IT	Information Technology
ASHI	American Society for Histocompatibility and Immunogenetics	IRB	Institutional Review Board
B-LCLs	B-Lymphoblastoid Cell Lines	KIR	Killer Immunoglobulin-like Receptor
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	NCI	National Cancer Institute
BRT	Basic Radiation Training	MHC	Major Histocompatibility Complex
C&A	Certification and Accreditation	MICA	MHC Class I-Like Molecule, Chain A
CBMTG	Canadian Blood and Marrow Transplant Group	MICB	MHC Class I-Like Molecule, Chain B
CBB	Cord Blood Bank	MUD	Matched Unrelated Donor
CBC	Congressional Black Caucus	NCBM	National Conference of Black Mayors
CBS	Canadian Blood Service	NIH	National Institutes of Health
CBU	Cord Blood Unit	NIMS	National Incident Management System
CHTC	Certified Hematopoeitic Transplant Coordinator	NK	Natural Killer
CIBMTR	Center for International Blood & Marrow Transplant Research	NMDP	National Marrow Donor Program
CLIA	Clinical Laboratory Improvement Amendment	NRP	National Response Plan
CME	Continuing Medical Education	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CREG	Cross Reactive Groups	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CT	Confirmatory Testing	OIT	Office of Information Technology
CTA	Clinical Trial Application	OMB	Office of Management and Budget
DIY	Do it yourself	ONR	Office of Naval Research

DKMS	Deutsche Knochenmarkspenderdatei	PBMC	Peripheral Blood Mononuclear Cells
DMSO	Dimethylsulphoxide	PBSC	Peripheral Blood Stem Cell
DNA	Deoxyribonucleic Acid	PCR	Polymerase Chain Reaction
D/R	Donor/Recipient	PSA	Public Service Announcement
EBMT	European Group for Blood and Marrow Transplantation	QC	Quality control
EM	Expectation Maximization	RCC	Renal Cell Carcinoma
EMDIS	European Marrow Donor Information System	REAC/TS	Radiation Emergency Assistance Center/Training Site
FBI	Federal Bureau of Investigation	RFP	Request for Proposal
FDA	Food and Drug Administration	RFQ	Request for Quotation
Fst	Fixation Index	RITN	Radiation Injury Treatment Network
GETS	Government Emergency Telecommunications Service	SBT	Sequence Based Typing
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SCTOD	Stem Cell Therapeutics Outcome Database
GvHD	Graft vs Host Disease	SG	Sample Group
HHS	Health and Human Services	SSP	Sequence Specific Primers
HIPAA	Health Insurance Portability and Accountability Act	SSOP	Sequence Specific Oligonucleotide Probes
HLA	Human Leukocyte Antigen	STAR®	Search, Tracking and Registry
HML	Histoimmunogenetics Mark-up Language	TC	Transplant Center
HR	High Resolution	TED	Transplant Essential Data
HRSA	Health Resources and Services Administration	TNC	Total Nucleated Cell
HSC	Hematopoietic Stem Cell	TSA	Transportation Security Agency
IBWC	Immunobiology Working Committee	URD	Unrelated Donor
IDM	Infectious Disease Markers	WMDA	World Marrow Donor Association
IHWG	International Histocompatibility Working Group	WU	Work-up

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U	U	U			19b. TELEPONE NUMBER *(Include area code)* 612.362.3425